

the final Office Action. Thus, Applicant assumes that claim 93 contains allowable subject matter. It is respectfully requested that the Examiner clearly indicate the allowable status of claim 93 in the next Office communication to Applicant. If, however, the Examiner intended a rejection of that claim, Applicant respectfully requests that the Examiner set forth a detailed explanation of the basis for that rejection and make any subsequent Office Action non-final to provide Applicant with a full and fair opportunity to respond.

For the following reasons, Applicant respectfully requests withdrawal of all the outstanding rejections and allowance of all pending claims.

**I. 35 U.S.C. § 103(a) Rejection Based on Konomura and Levinson**

Claims 1-4, 8, 10-18, 23-30, 33-40, 42-44, 46, 47-52, 54, 56, 58-63, and 65-68 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura ("Konomura") in view of U.S. Patent No. 6,660,011 to Levinson ("Levinson"). See pages 2-5 of final Office Action. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Each of independent claims 1 and 34 is directed to a medical device including "an elongated member" and "a tissue cutting end effector proximate the distal end of the elongated member." Claim 1 further recites, among other things, "a distal member," whereas claim 34 recites, among other things, "a nozzle member."

Each of independent claims 47 and 59 is directed to a method of performing a medical procedure. Claim 47 recites "inserting a medical device into a tissue tract of a patient," the medical device including a nozzle member and a tissue cutting end effector. The method further includes "actuating the tissue cutting end effector of the

medical device to sever the tissue of the tissue tract.” Claim 59 recites “inserting a medical device into a patient,” the medical device including an elongated member, a tissue cutting end effector, and a distal member. The method further includes “actuating the tissue cutting end effector to sever tissue of a tissue tract.”

In the rejection, the final Office Action admits that Konomura does not disclose “a tissue cutting end effector wherein actuation of the proximal handle causes the end effector to sever tissue.” (See page 3.) Nonetheless, the final Office Action asserts that “Levinson teaches of an analogous medical device used for tissue cutting and retrieval” and that “[i]t would have been obvious ... to have a tissue cutting end effector in the apparatus of Konomura to selectively capture, cut and/or retrieve polyps and other aggregates of organic tissue from a patient’s internal organs as taught by Levinson.” (See page 3.) Applicant respectfully submits that the final Office Action’s asserted combination of Konomura and Levinson fails to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

The Examiner has the initial burden of presenting a *prima facie* case of unpatentability. To establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), three basic criteria must be met. First, the prior art references when combined must teach or suggest all the claim elements. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally, there must be a reasonable expectation of success. See M.P.E.P. § 2143. Furthermore, case law in this context indicates that the teaching or suggestion to make the claimed combination and the reasonable expectation of success

must both be found in the prior art, and that the evidence of a teaching, suggestion, or motivation to combine must be “clear and particular.”

Konomura discloses a basket forceps assembly 1 comprising a hollow sheath 2 and a basket 3 that moves out of and into the front end of the sheath 2 for holding or fracturing a foreign matter. The basket 3 comprises a plurality of resilient wires 6 and a front end tip 7 to which the front ends of the wires 6 are secured. The front end tip 7 includes a notched groove 18, as shown in Fig. 3, or through openings 19a, 19b, as shown in Fig. 5. In alternative embodiments shown in Figs. 6-9, the sheath 2 includes an opening 20 or elongated slot 21, 22. The Konomura basket is for holding or fracturing calculi, stones, and the like found within the urologic tract, such as the bile duct or ureter. The basket is not for severing tissue from a tissue tract.

Different from the basket forceps assembly 1 of Konomura, Levinson discloses a device 10 for cutting and retrieving tissue. The device includes a handle 12, an elongated tube 14 extending from the handle 12, and first and second sets of wires 20, 28 slidable relative to the tube 14. A control tip 24 is secured to the distal ends 22 of the first set of wires 20. See, e.g., Figs. 2 and 3. To cut and retrieve tissue in a body cavity, as shown in Fig. 9, after the distal end of the tube 14 is inserted into the body cavity, the second set of wires 28 is first extended from the distal end of the tube 14 to capture and cut tissue. The first set of wires and the control tip 24 of the first wires are then extended from the distal end of the tube to capture the cut tissue between the first and second sets of wires 20, 28. Thereafter, the distal end of the tube 14, together with the first and second sets of wires, is withdrawn from the body cavity. See also col. 5, lines 39-57.

As detailed below, the asserted combination of Konomura and Levinson fails to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a). In particular, as to the second criterion for establishing a *prima facie* case of obviousness, there is no suggestion or motivation in either Konomura or Levinson to combine or modify the asserted teachings of the references in the manner proposed by the final Office Action. The final Office Action asserts that, since Levinson merely discloses an end effector that cuts and retrieves tissue, it would have been obvious to have Levinson's end effector in the device of Konomura "to selectively capture, cut and/or retrieve polyps and other aggregates of organic tissue from a patient's internal organs as taught by Levinson." However, this asserted motivation is merely a conclusory statement and does not provide any sufficient, factual reasoning as to why selectively capturing, cutting, and/or retrieving polyps and other aggregates of organic tissue would have been desired by one of ordinary skill in the art considering Konomura's device. For example, there is no teaching or suggestion in Konomura that its basket forceps assembly needs or desires a tissue cutting capability. Nor does Levinson teach or suggest it does. Although Levinson teaches combining a tissue cutting snare and a basket retriever in one device to cut and retrieve tissue, it does not teach that such a tissue cutting capability is desirable in the device of Konomura, which is typically used in urology applications to hold or fracture a gallstone or ureteral calculus. Thus, there is no clear and particular reason supplied by either Konomura or Levinson that would have motivated one skilled in the art to modify the basket forceps assembly of Konomura in the manner proposed by the final Office Action.

The final Office Action's asserted motivation is a result of impermissible hindsight gleaned from the present application, which discloses novel and non-obvious subject matter of, for example, a tissue cutting end effector having a spray mechanism. When the references are viewed without such hindsight, one of ordinary skill in the art considering Konomura's device would not have been motivated to modify the device in the manner proposed by the final Office Action since there is no "clear and particular" reason to do so. For at least these reasons, a *prima facie* case of obviousness under 35 U.S.C. § 103(a) has not been properly established.

Moreover, with respect to method claims 47-54, 56-68, and 89-96, the final Office Action asserts that "[t]he apparatus of Konomura and Levinson is inherently capable of performing the recited method steps." Applicant respectfully disagrees with this assertion because the final Office Action has improperly relied on an inherency principle.

For a proper inherency-based rejection, the Office must provide a factual basis and/or technical reasoning to reasonably support its determination that the missing feature is necessarily present in the subject matter described in the reference. In general, mere probabilities or possibilities that certain subject matter may result from a given set of circumstances is not sufficient to establish inherency. See generally M.P.E.P. § 2112. Thus, whether a device in a prior art reference is inherently capable of performing recited method in a claim is completely irrelevant in determining whether that reference discloses the method. Instead, to properly rely on the inherency principle, the Office must show that the normal and usual operation of the device in the

prior art reference must necessarily perform the recited method. See, e.g., M.P.E.P. 2112.02.

Therefore, the rejection of claims 47-54, 56-68, and 89-96 based on the assertion that “[t]he apparatus of Konomura and Levinson is inherently capable of performing the recited method steps” is erroneous.

Moreover, it is not even clear what the so-called “apparatus of Konomura and Levinson” would be and what applications it would have. Consequently, it is unclear what “the normal and usual operation” of that apparatus would be. Since the “the normal and usual operation” of that apparatus is unclear, relying on the inherency principle and asserting that the apparatus inherently teaches all of the recited methods would be completely baseless and erroneous. Therefore, even if the Office were to properly rely on the inherency principle with respect to claims 47-54, 56-68, and 89-96, the inherency principle would not apply at least because “the normal and usual operation” of the “apparatus of Konomura and Levinson” is unknown.

For at least the reasons set forth above, reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a) is respectfully requested.

## **II. 35 U.S.C. § 103(a) Rejection Based on Konomura, Levinson, and McAlister**

Claims 5-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Konomura in view of Levinson and further in view of U.S. Patent No. 5,599,324 to McAlister et al. (“McAlister”). See pages 5 and 6 of final Office Action. Applicant respectfully requests reconsideration and withdrawal of this rejection since claims 5-7 depend directly or indirectly from independent claim 1. As discussed above, independent claim 1 patentably distinguishes from the asserted combination of

Konomura and Levinson, and McAlister does not supply the deficiency of Konomura and Levinson.

**III. 35 U.S.C. § 103(a) Rejection Based on Konomura, Levinson, and Smith**

Claims 19-21, 41, 57, 83-86, 90-92, and 94-96 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Konomura in view of Levinson and further in view of U.S. Patent No. 6,517,539 to Smith et al. ("Smith"). See page 6 of final Office Action. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

**Claims 41, 57, 90-92, and 94-96**

Claim 41 depends indirectly from independent claim 34, claims 57 and 90-92 depend directly or indirectly from independent claim 47, and claims 94-96 depend directly or indirectly from independent claim 59. As discussed above, independent claims 34, 47, and 59 patentably distinguish from the asserted combination of Konomura and Levinson. Also, Smith does not supply the deficiency of Konomura and Levinson. Therefore, claims 41, 57, 90-92, and 94-96 should also patentably distinguish from the asserted combination of Konomura, Levinson, and Smith for the same reason that independent claims 34, 47, and 59 are patentable over the asserted combination of Konomura and Levinson. Thus, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection as applied to claims 41, 57, 90-92, and 94-96.

**Claims 19-21**

Independent claim 19 recites a medical device comprising, among other things, "an elongated member having a proximal end, a distal end, and a lumen therebetween,"

“an end effector proximate the distal end of the elongated member,” and “a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member,” “wherein the distal member fixedly connects to the end effector at a proximal end of the end effector.”

As discussed above in Section I, the asserted combination of Konomura and Levinson fails to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a). Applicant’s reasons supplied therein are also applicable for this ground of rejection and, for those reasons alone, this ground of rejection should be withdrawn.

Furthermore, as mentioned above, claim 19 recites that “the distal member [i.e., configured to open and substantially close the distal end of the lumen and defining a flow path] fixedly connects to the end effector at a proximal end of the end effector.” As explained below, none of the cited references, taken either singularly or in combination, teaches or otherwise suggests, among other things, this feature of claim 19.

The final Office Action admits that both Konomura and Levinson are silent with respect to this feature. Nevertheless, the final Office Action asserts that “Smith et al. teach of an analogous device having a distal member 96 fixedly secured to proximal end of the end effector 24 (see Figs. 12-13)” and that “[i]t would have been obvious ... to include a fixedly secured distal member in the apparatus of Konomura and Levinson in order to provide greater control over the end effector as taught by Smith et al.”

Smith discloses a surgical snare instrument 10 having a tubular sheath 12, a flexible shaft 18 extending through and axially movable relative to the sheath 12, and a



snare 24 coupled to a distal end of the shaft 18. In one exemplary embodiment, the snare 24 can be coupled to the distal end of the shaft 18 by a crimp band 96, as best shown in Figs. 12 and 13. The final Office Action asserts that this crimp band 96 allegedly corresponds to the recited “distal member.”

The crimp band 96 of Smith, however, is not “configured to open and substantially close the distal end of the lumen.” Nor does it define any flow path therein. Therefore, the crimp band 96 cannot correspond to the recited “distal member.”

In addition, even assuming, for the sake of argument, that the crimp band 96 of Smith corresponds to the recited “distal member,” the asserted teachings of Smith would not have motivated one skilled in the art considering the device of Konomura to include such a distal member at the proximal end of its end effector because, among other reasons, it would destroy the teachings of Konomura. For example, that added distal member would fill space within the lumen of hollow sheath 2 of Konomura when the front end tip 7 is fitted onto the distal end of the sheath 2, thereby hampering the fluid injection operation of the device. For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this ground rejection as applied to claims 19-21.

#### **Claims 83-86**

Independent claim 83 recites a medical device comprising, among other things, “an elongated member having a proximal end, a distal end, and a lumen therebetween,” “an end effector proximate the distal end of the elongated member,” and “a distal member configured to open and substantially close the distal end of the lumen and defining a flow path.” The distal member comprises “a main body connected to a proximal end of the effector” and “an annular body fixed to the distal end of the

elongated member, wherein the main body and the annular body are configured to contact each other to substantially close the distal end of the lumen, and wherein, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member.”

As discussed above in Section I, the asserted combination of Konomura and Levinson fails to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a). Applicant’s reasons supplied therein are also applicable for this ground of rejection and, for those reasons alone, this ground of rejection should be withdrawn.

Furthermore, none of the cited references, taken either singularly or in combination, teaches or suggests, among other things, the claimed distal member. The final Office Action does not explain how the cited references, alone or in combination, teaches or suggests the recited “main body” or “annular body” that are configured to contact each other to substantially close the distal end of the lumen. As explained above in the discussion of claims 19-21, the asserted combination of Konomura, Levinson, and Smith clearly does not teach a distal member or main body fixedly attached to the proximal end of an end effector. Furthermore, none of the cited references, taken either singularly or in combination, teaches or suggests, among other things, an annular member that contacts with the main body to substantially close the distal end of the lumen.

Should the Office maintain this ground of rejection, Applicant respectfully requests that the Examiner clearly explain how the cited references teaches or suggests all of the recited elements of claim 83, so as to enable Applicant to better understand the final Office Action’s position and respond to the Office.

For at least the reasons set forth above, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

**IV. 35 U.S.C. § 103(a) Rejection Based on Konomura, Levinson, and Hawkins**

Claims 31, 32, 45, 53, and 64 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Konomura in view of Levinson and further in view of U.S. Patent No. 5,575,694 to Hawkins et al. ("Hawkins"). See pages 6 and 7 of final Office Action. Applicant respectfully requests reconsideration and withdrawal of this rejection, since each of these claims depends directly or indirectly from independent claim 1, 34, 47, or 59. As discussed above, independent claims 1, 34, 47, and 59 patentably distinguish from the asserted combination of Konomura and Levinson, and Hawkins does not supply the deficiency of Konomura and Levinson.

**V. 35 U.S.C. § 103(a) Rejection Based on Konomura, Levinson, and Moutafis**

Claims 69-82 and 87-89 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Konomura in view of Levinson and further in view of U.S. Patent No. 6,960,182 to Moutafis et al. ("Moutafis"). See pages 7 and 8 of final Office Action. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Each of independent claims 69 and 87 is directed to a medical device comprising, among other things, "an elongated member having a proximal end, a distal end, and a lumen therebetween" and "a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the

elongated member.” Independent claim 69 further recites that “at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path.” Independent claim 87 further recites that “the flow path comprises an inlet and a plurality of outlets connecting to the inlet.”

As discussed above in Section I, the asserted combination of Konomura and Levinson fails to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a). Applicant’s reasons supplied therein are also applicable for this rejection and, for those reasons alone, this ground of rejection should be withdrawn.

Moreover, none of the cited references, taken either singularly or in combination, teaches or suggests, among other things, a flow path having “a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path,” as recited in claim 69, and a flow path having “an inlet and a plurality of outlets connecting to the inlet,” as recited in claim 87. The Examiner admits that Konomura and Levinson are silent with respect to these features. Nevertheless, the Examiner asserts that Moutafis teaches “a nozzle capable of having a large variety of configurations and cross-sectional flow paths to effect the outputted fluid (see Cols. 21 and 22 and Figs. 3a-e)” and, therefore, “it would have been obvious ... to vary the cross-sectional flow area in the apparatus of Konomura and Levinson in order to have greater control over the outputted flow of fluid as taught by Moutafis et al.” With respect to claims 87-89, the final Office Action does not even explain how the cited references allegedly teach or suggest all of the claim elements.

As mentioned above, to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), one of three basic criteria requires that the prior art references when combined must teach or suggest all the claim elements. Nowhere in Konomura, Levinson, or Moutafis, however, is there any teaching or suggestion that a flow path in the distal member has “a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path,” as recited in claim 69, or that a flow path has “an inlet and a plurality of outlets connecting to the inlet,” as recited in claim 87. The configurations specifically referred to in Figs. 3a-3e of Moutafis do not disclose any of the flow path configurations of claims 69 and 87.

In fact, the final Office Action does not allege otherwise. Instead, the final Office Action erroneously asserts that, merely because Moutafis allegedly teaches that its nozzle can have various configurations, it would have been obvious to modify the apparatus of Konomura and Levinson (whatever that combined apparatus may be) to arrive at the claimed invention. This assertion is insufficient to establish a *prima facie* case of obviousness. As mentioned above, the prior art references when combined must teach or suggest all the claim elements. The mere fact that a nozzle can have various configurations does not specifically teach one of ordinary skill in the art to arrive at the recited flow path configurations of claims 69 and 87.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

**VI. Conclusion**

Applicant respectfully requests reconsideration of this application, withdrawal of all the outstanding rejections, and allowance of all pending claims.

The final Office Action contains a number of statements and characterizations regarding the claims and the related art. Applicant declines to necessarily subscribe to any statement or characterization in the final Office Action, regardless of whether it is addressed above.

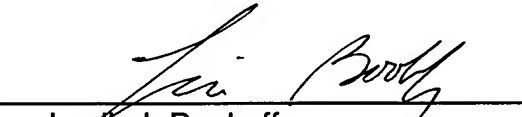
Should the Examiner wish to discuss this case, he is invited to call the undersigned at 202-408-4140.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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